

## **REMARKS**

### **Section 112 Rejections:**

In the Office Action dated March 25, 2003, the Examiner rejected claims 13-16 under 35 U.S.C. § 112 for failing to particularly point out and distinctly claim the subject matter which application regards as the invention.

Applicant has offered amendments to claims 13-16 to overcome the indefiniteness complained of by the Examiner and to correct an incorrect dependency reference. Applicant has clarified that the beverages in question have tastes and aromas which simulate the taste and aroma of specific alcohol containing beverages. Such non-alcoholic beverages are well known and understood in the industry.

“In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 25 U.S.C. 112, second paragraph.” MPEP 2173.02 at 2100-194 (8<sup>th</sup> ed. 2001), *citing Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). Persons having ordinary skill would understand references to non-alcoholic beverages having tastes and aromas simulating those of alcoholic beverages. As amended, the claims meet the clarity requirements of Section 112.

### **Section 102 Rejections:**

In the Office Action dated March 25, 2003, the Examiner rejected claims 1-2 under 35 U.S.C. § 102 as being clearly anticipated by both ‘998 (Holzer) and Kryspin (1974).

In claims 1 and 2, Applicant claim a method of treating alcohol *craving* by administering a composition comprising an effective amount of one or more apha-pyrone compounds found in the plant *Piper methysticum*.

Holzer teaches a beer to which an extract of the kava plant is added “not with a view of replacing the hops but with a view of giving the beer new properties *i.e.* thirst quenching, tonic and diuretic properties. . . .” Holzer, col. 1, lines 23-26. Holzer does not teach a method of treating alcohol craving or of treating any psychological or physiological disorder.

Krsypine teaches using kavain, an ingredient found in the kava plant, to treat chronic abstinence syndrome, being the withdrawal symptoms experienced by alcoholic patients in the withdrawal phase. Kryspin, Abstract. Kryspin does not teach a method of treating alcohol *craving*. See discussion of the distinction between craving and withdrawal syndromes below. Krystpine also does not teach a method of treating alcoholism using any alpha-pyrone or kavalactone compound found in the plant *Piper methysticum* other than kavain.

The Examiner states that a reduction in the symptoms associated with alcohol withdrawal would reduce craving for alcohol since patients would not desire alcohol to combat the symptoms of alcohol withdrawal. However, as discussed below, the phenomena of alcohol craving can be entirely independent of alcohol withdrawal symptoms and alcoholics continue to crave alcohol notwithstanding the cessation of alcohol withdrawal symptoms. Accordingly, agents that treat alcohol craving are new and distinguishable from agents that treat alcohol withdrawal symptoms but do not treat the alcohol craving that occurs separate and apart from the withdrawal.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” TEMP § 2131 at 2100-69 (8<sup>th</sup> Ed. 2001), *quoting Verdegaal Bros. v. Union Oil Co. Of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir, 1987). Neither Holzer nor Krsypine teach an agent that treats alcohol craving, to wit, an agent that reducing craving and/or alcohol consumption in the absence of alcohol withdrawal symptoms.

Accordingly claims 1 and 2 describe methods for the treatment of alcohol craving which are not anticipated by the prior art and which are novel within the meaning Section 102 of the Patent Act.

Section 103 Rejections:

In the Office Action dated March 25, 2003, the Examiner rejected under 35 U.S.C. § 103(a) as being obvious, *inter alia*, claims 1-2 in light of Kryspin; claims 1-3 and 5 in light of Kryspin in combination with Gillmer (1973) and Cody ('825); claims 1-5 in light of Kryspin in combination with Gillmer, Cody and Hinton ('542); and claims 10-11 and 13-15 in light of Kryspin in combination with Lemert (1976) and Schur ('355).

Cody and Hinton Are Not Prior Art.

The subject application claims the benefit of provisional application no. 60/141,805 filed June 29, 1999. The effective filing date of the subject application is therefore June 29, 1999. 35 U.S.C. § 119(e); MPEP § 706.02 at 700-2 (8<sup>th</sup> ed. 2001). The effective filing date of the application must be determined and compared with the date of the prior art references. *Ibid.*, § 706.02(a) at 700-21.

Cody, issued April 4, 2000, and Hinton, issued January 16, 2001, were both published subsequent to the June 29, 1999 effective filing date of the subject application. Neither reference formed a part of the prior art at the time Applicant filed his provisional application. Accordingly, these references should not be cited against Applicant for purposes of challenging the Section 103 non-obviousness requirement.

Alcohol Craving is Separate and Distinct From Alcohol Withdrawal as is the Treatment of Each

The treatment of craving is separate and distinct from the treatment of withdrawal symptoms. Drug craving has been defined as “the desire to experience the effects of a previously experienced psychoactive substance.” Bender, Drug Craving Distinguished from Withdrawal Symptoms, *Psychiatric Times*, 1995: 12(9)(a copy of which is enclosed with this Amendment and Response), quoting the United Nations International Drug Control Programme and the World Health Organization 1992 Expert Committee to define the term craving. Drug craving is a “multidimensional phenomenon that consists of subjective, behavioral, physiological and neurochemical correlates.” Bender, quoting Markou et al, Animal models of drug craving, *Psychopharmacology (Berl.)* 1993; 112(2-3): 163-182.

Somoza identified eight symptoms generally associated with drug withdrawal: anxiety, depression, restlessness, anger, irritability, frustration, impatience and poor concentration. Bender, citing Somoza et al, In search of a universal drug craving scale (presented at the 148<sup>th</sup> Annual American Psychiatric Association Meeting, May 25, 1995; Miami Beach, Fla.). Many of these symptoms are the same as those which the Examiner references Kryspin as teaching the reduction of through the use of kavain.

In a study conducted by Medzinskis et al., it was concluded that drug craving is a phenomena separate and distinct from drug withdrawal. Bender; Mezinskis et al., Drug craving verses withdrawal symptoms: Are they different? (presented at the 148<sup>th</sup> Annual American Psychiatric Association Meeting, May 25, 1995, Miami Beach, Fla.); Mezinskis et al., Craving and Withdrawal Symptoms for Various Drugs of Abuse, *Psychiatric Annals* 1998; 28:10, 577-583 (a copy of which is enclosed with this response). This conclusion is further substantiated by a study conducted by Pickering & Liljequist wherein it was demonstrated that environmental cues could increase the craving for alcohol in rats not experiencing alcohol withdrawal or relapse. Pickering et al., *PMID*: 12684740 (PubMed)(a copy of the abstract of which is enclosed with this response).

Because craving is often separate and distinct from withdrawal symptoms attributed to substance abuse, both the craving and the withdrawal need to be treated in order to provide a comprehensive program for addiction rehabilitation. This is substantiated by the fact that cravings for drugs often remain high even upon completion of drug rehabilitation programs when all symptoms related to drug withdrawal have ceased. Bender; Mezinskis et al. Researchers are searching for agents capable of attenuating craving separate and apart from agents useful in reducing withdrawal symptoms. Among these efforts are FDA approved open trials of naltrexone. Bender.

Claim 1:

In independent claim 1, Applicant claims a method of treating alcohol craving by administering an effective amount of one or more alpha-pyrone compounds.

Kryspin teaches using kavain, an ingredient found in the kava plant, to treat chronic abstinence syndrome, being the withdrawal symptoms experienced by alcoholic patients in the withdrawal phase. Kryspin, Abstract. Kryspin does not teach a method of treating alcohol *craving*.

Gillmer describes a study in which the effects of benzoctamine and oxazepam on the anxiolytic and resocializing symptoms of alcohol withdrawal syndrome were measured. Gillmer does not teach a method of treating alcohol craving, nor a method of treatment utilizing the kava plant or kava-pyrones.

Cody teaches the use of the kava plant *Piper methysticum* to diminish the desire for tobacco as a result of the plant's ant-depressive and anti-anxiety effects without sedative or hypnotic effects. Cody does not teach a method of treating alcohol craving. Cody is also not a part of the published art that precedes this application.

Hinton teaches a dietary supplement that contains as one of several of its ingredients kava kava for treating, preventing, alleviating or managing symptoms associated with premenstrual syndrome (PMS) in women. Hinton does not teach a method of treating craving

separate from withdrawal, nor a method for treating any aspect of the disease alcoholism. Hinton is also not a part of the published art that precedes this application.

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03 at 2100-126, *citing In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis supplied).

Independent claim 1, a method of treating alcohol craving, would not have been obvious to one having ordinary skill in the applicable art in light of Kryspin, Gillmer, Cody, and/or Hinton because none of these cited reference, individually or in combination, teach, suggests or imply a method of treating craving independent from symptoms that accompany withdrawal.

It was well known at the time of study reported in Kryspin that ingredients found in the kava plant can function as an anxiolytic or anti-anxiety agent. Those having ordinary skill in the pertinent art could infer therefrom that the kava plant would be useful in treating physiologic symptoms that manifest during substance abuse withdrawal. The Kryspin study supports this inference in the case of alcoholism.

In contrast, and as illustrated by the discussion of Bender and Mezinskis above, the distinction between phenomena that comprise craving and phenomena that comprise withdrawal symptoms is poorly appreciated even among those skilled in the art of substance abuse. It does not follow that because ingredients found in the kava plant have anxiolytic effects, these ingredients would be useful in reducing craving in individuals not experiencing drug withdrawal. Nothing in the cited prior art teaches or suggests such a relationship.

Cody claims to teach the use of the kava plant to diminish the desire for tobacco. A close examination of the Cody specification, however, reveals that Cody is describing a method of treating the symptoms of tobacco withdrawal, not the craving that exists independent from these withdrawal symptoms. According to Cody, “[a]n important factor in nicotine addition is the discomfort and difficulty which accompanies the depressive effects and increased anxiety associated with a nicotine withdrawal after the tobacco user has ceased consuming nicotine-

containing products”. Cody, col. 3 lines 63-67. “[T]he composition of the present invention provides an all natural anti-depressive and anti-anxiety properties [sic] to counter the depression that is commonly associated with nicotine withdrawal; and therefore, by countering this important factor, one major difficulty of nicotine withdrawal is alleviated. . . .” Cody, col. 4, lines 22-27. Cody does not teach, suggest or imply the use of the kava plant to treat craving that occurs in absence of withdrawal symptoms. More importantly, Cody did not form a part of the publically available prior art at the time the provisional application upon which the subject application is based was filed.

The present invention provides an effective solution to a long-felt but to date unsatisfied need. “Clinically, the [post -withdrawal] type of craving is the most important, because it may be useful in explaining relapse.” Mezinskis et al., at 577. Agents to keep recovering alcoholics “on the wagon” are just as important, if not more important, compared with those which assist the substance abuser with withdrawal symptoms during the detoxification period. The existence of a long-felt but unsatisfied industry need is evidence of non-obviousness. *Expanded Metal Co. v. Bradford*, 214 U.S. 366 (1909); *Shackelton v. J. Kaufman Iron Works, Inc.*, 689 F.2d 334, 338. 340-41 (2d Cir. 1982), *cert. denied*, 460 U.S. 1052 (1983). Accordingly, it would not have been obvious to one having ordinary skill in the art of treating substance abuse to apply the teachings of Kryspin, Gillmer, Cody, and/or Hinton, individually or in combination, to devise a method for treating alcohol *craving* using the kava plant or the active ingredients found therein.

Claim 13:

In independent claim 13 Applicant claims a non-alcoholic beverage having a taste and aroma that simulates an alcoholic beverage containing an effective amount of one or more alpha-pyrone compounds.

Kryspin teaches using kavain, an ingredient found in the kava plant, to treat the withdrawal symptoms experienced by alcoholic patients in the withdrawal phase.

Lemert provides an anthropological account of the orange-beer culture of the Cook Islands. Lemert uses the term kava to describe alcoholic beer made from oranges. Lemert does not describe any substances made from the kava plant *Piper methysticum*, nor any beverage, alcoholic or non-alcoholic, containing kava-pyrone.

Schur describes a process for the preparation of alcohol-free drinks having a yeast aroma and beer-like taste. Schur does not describe a beverage containing the kava plant or any of the pharmaceutical agents that may be found therein.

“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. . . . [T]here must be a suggestion or motivation in the reference to [modify or combine it].” MPEP § 2143.01 at 2100-124 (emphasis in the original), *citing In re Mills*, 916 F.2d 680 at 682, 16 USPQ2d 1430 (Fed. Cir. 1990). Kryspin, Lemert and Schur are taken from different fields, adopt different approaches, seek different solutions, or require modification in order to solve the problems that are solved by the instant invention, modifications which are neither taught nor suggested. It would not have been obvious to one of ordinary skills in a pertinent field to combine Kryspin, Lemert and/or Schur to provide a kava-pyrone containing non-alcoholic beer, wine or distilled spirit beverage.

Dependent Claims:

“If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious”. MPEP § 2143.03 at 2100-126, *citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Dependent claims 2 through 6 and 10 through 12 include all limitations found in independent claim 1. Dependent claims 14 through 16 include all limitations found in independent claim 13. Dependent claims 2 through 6, 10 through 12 and 14 through 16 are therefore new and unobvious for the same reasons as independent claims 1 and 13.



## CONCLUSION

Applicant has offered amendments to claims 13 to 16 with clarifying language to overcome the Examiner's Section 112 rejection. Applicant has presenting evidence and argument establishing that independent claims 1 and 13 describe subject matter that is both new and unobvious, and should be allowed. As dependent claims 2 through 6 and 10 through 12 include all limitations found in independent claim 1, and dependent claims 14 through 16 include all limitations found in independent claim, the pending dependent claims should likewise be allowed.

The Examiner is invited to contact the undersigned attorney at (808) 523-8984, business hours Hawaii standard time, or via email at <[sethreiss@lawhi.com](mailto:sethreiss@lawhi.com)>, in order that the undersigned attorney may endeavor to resolve any outstanding issues as expeditiously as possible thereby to avoid prolonged prosecution of the present application.

This paper is being mailed with a certificate within four months of the March 25, 2003 mailing date of the Office Action to which it responds, being within the first month beyond the statutory three month period for response. A \$55 small entity fee for a one month extension to respond is enclosed. The number of independent claims and the total number of claims, after amendment, are within the number paid for with the filing fee.

Respectfully submitted,



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